DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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March 25, 2015

Shenyi Shandong Plastic Products, Co. Ltd.
C/O Mr. Ray Zhou
Official Correspondent
Basic Medical Industries, Inc.
12390 East End Ave.
Chino, CA 91710

Re: K142892
Trade/Device Name: Powder-Free Clear Vinyl Patient Examination Gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LYZ
Dated: February 13, 2015
Received: February 23, 2015

Dear Mr. Zhou:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
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Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K142892

Device Name

Powder-free Clear Vinyl Patient Examination Gloves

Indications for Use *(Describe)*

A patient examination glove is a disposable device intended for medical purposes that is worn upon the examiner's hands or fingers to prevent contamination between patient and examiner.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☑ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Submitter's Name and Address:

Shenyi (Shandong) Plastic Products, Co. Ltd.
No.23 Fenghuang Road
Fengshan Industry Park Linzi
Shandong, 255400 China

Contact Person:

Minghao Shi, Marketing Manager
Phone: # 86-533 7527018

Date Summary prepared: March 19, 2015

Name of the Device:

Powder-free Clear Vinyl Patient Examination Gloves

Assigned 510(k) Number

K142892

Common name/classification name of the Device:

Patient Examination Glove
Device Class: Class I
Regulation number: 21 CFR 880.6250
Product code: LYZ

Predicate Device Information:

Device name: Vinyl Examination Gloves, Powder-Free
510(K) #: K022091
Manufacturer name: Tangshan Zhonghong Pulin Food Products Co., Ltd

Device Description:

The subject device is Powder-Free Vinyl Patient Examination Gloves that is worn upon the examiner's hands or finger. As a barrier, the subject device prevents contamination between patient and examiner. The subject device meets all of the requirements of ASTM standards D5250-06 for Physical and performance characteristics, D5151-06 for barrier properties and D6124-06 for residual powder.

Indications for Use:

The subject device is a disposable device intended for medical purposes that is worn upon the examiner's hands or finger to prevent contamination between patient and examiner.

Comparison to Predicate Devices:

Powder-free Clear Vinyl Patient Examination Gloves (K142892) is substantially equivalent to the Vinyl Examination Gloves, Powder-Free (K022091).

Substantial Equivalence Comparison Table

	Proposed Device (K142892)	**Predicate Device (K022091)**	**COMMENTS**
The device	Shenyi (Shandong) Plastic Products, Co. Ltd. Powder-free Clear Vinyl Patient Examination Gloves	Vinyl Examination Gloves, Powder-Free Tangshan Zhonghong Pulin Food Products Co., Ltd	
Regulation #	21 CFR 880.6250	21 CFR 880.6250	Substantially equivalent
Device Class	Class I	Class I	Substantially equivalent
Product Code:	LYZ	LYZ	Substantially equivalent
Indications for Use	Disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner	Disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner	Substantially equivalent
Basic Design	Cover the hand and wrist area. Clovers have separate sheaths or openings for each finger and the thumb.	Cover the hand and wrist area. Clovers have separate sheaths or openings for each finger and the thumb.	Substantially equivalent
Device Materials	Poly Vinyl Chloride	Poly Vinyl Chloride	Substantially equivalent
Residual Powder	<2 mg per glove Conform to ASTM D6124-06.	< 2 mg per glove Conform to ASTM D6124	Substantially equivalent
Length on Large Size	Conform to ASTM D5250, 2011	Conform to ASTM D5250 2002	Substantially equivalent
Width of Palm on Large Size	Conform to ASTM D5250, 2011	Conform to ASTM D5250 2002	Substantially equivalent
Palm Thickness	Conform to ASTM D5250, 2011	Conform to ASTM D5250 2002	Substantially equivalent
Fingertip Thickness	Conform to ASTM D5250, 2011	Conform to ASTM D5250 2002	Substantially equivalent

Before & After Aging: Tensile Strength(Mpa) and Ultimate Elongations	≥11MPa (Tensile strength) ≥360% (elongation) Conform to ASTM D5250-06	≥11MPa (Tensile strength) ≥360% (elongation) Conform to ASTM D5250	Substantially equivalent
Pinhole Results	AQL 2.5 Conform to ASTM D5151-06	AQL 2.5 Conform to ASTM D5151	Substantially equivalent
Primary Skin Irritation Per ISO-10993-10	Not an irritant under the condition of study	Not an irritant under the condition of study	Substantially equivalent
Dermal Sensitization Per ISO-10993-10	Not a sensitizer under the condition of study	Not a sensitizer under the condition of study	Substantially equivalent
Labeling	Labels include: Product name; Non-sterile; color; "single use Only" size, Quantity, ambidextrous, lot number, distributor name, indication for use and manufacturer address.	Labels include: Product name; Non-sterile; color; "single use" size, Quantity, ambidextrous, distributor name, indication for use and manufacturer address.	Substantially equivalent
Substantial equivalence	The subject device in K142892, Powder-free Clear Vinyl Patient Examination Gloves, has similar indications for use, design, material, physical and barrier properties and Biocompatibility and is substantially equivalent to the predicate device (K022091).		

Discussion of Non-Clinical tests performed for Determination of Substantial Equivalence are as follows:

Non-clinical tests were conducted on the subject device.

The dimensions and physical properties tests followed ASTM D5250-06 and met AQL 2.5, inspection level S-2.
The barrier test followed ASTM D5151-06 and met AQL 2.5, inspection level S-1.
Residual powder test followed ASTM D6124 and met the requirement of powder-free glove.
Biocompatibility test followed ISO 10993-10 showing no primary skin irritation or sensitization, under the conditions of study.

The subject device met the requirements of non-clinical tests, and performed similar to the predicate device.

Sterilization

The subject device is non-sterile examination gloves for single use.

Discussion of Clinical Tests Performed:

Not Applicable

Conclusions:

Powder-free Vinyl Patient Examination Glove, the subject device in K142892, has similar Indications for Use and technological characteristics, and is substantially equivalent to the predicate device (K022091).